Complete Summary

GUIDELINE TITLE

Recommendations to prevent hepatitis B virus transmission-United States-Update.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Update: recommendations to prevent hepatitis B virus transmission--United States. MMWR Recomm Rep 1999 Jan 22;48(2):33-4. [7 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Hepatitis B

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update all previous recommendations on protection against hepatitis B virus infection, including use of hepatitis B vaccine and hepatitis B immune globulin for prophylaxis against hepatitis B virus infection and universal screening of pregnant women to prevent perinatal hepatitis B virus transmission.
- To provide the rationale for a comprehensive strategy to eliminate transmission of hepatitis B virus in the United States.

TARGET POPULATION

- Persons aged 0-18 years
- Pregnant Women
- Persons at high risk of hepatitis B infection, including health care workers, public safety workers, clients and staff of institutions for the developmentally disabled, hemodialysis patients, recipient of certain blood products, household contacts and sex partners of hepatitis B virus carriers, adoptees from countries where hepatitis B virus infection is endemic, international travelers, injecting drug users, sexually active homosexual and bisexual men, sexually active heterosexual men and women, and inmates of long-term correctional facilities

INTERVENTIONS AND PRACTICES CONSIDERED

Prophylaxis

1. Hepatitis B vaccine for pre- and postexposure prophylaxis:
    - Recombivax HB
    - Engerix-B

    (These vaccines may or may not contain thimerosal, a mercury-containing preservative)

2. Hepatitis B immune globulin (HBIG) for postexposure prophylaxis only

MAJOR OUTCOMES CONSIDERED

- Efficacy, immunogenicity, and safety of hepatitis B vaccine
- Efficacy of postexposure prophylaxis
- National (US) vaccine coverage among children

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not applicable

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse: The foundation for these recommendations is the 1991 Advisory Committee on Immunization Practices' (ACIP) comprehensive hepatitis B vaccination strategy. Two subsequent ACIP updates are reflected in these recommendations:

- 1994 expanded recommendations to vaccinate previously unvaccinated children 11-12 years old and unvaccinated children less than 11 years old who are in populations at high risk
- 1997 expanded yet simplified recommendations to vaccinate previously unvaccinated children aged 0-18 years

Additionally, excerpts from the 1999 ACIP's recommendations for the use of vaccines that contain the preservative thimerosal are integrated into these recommendations. Finally, the 2000 ACIP's recommendations to include an alternate two-dose schedule for adolescents aged 11-15 years are noted.

Prophylaxis Against Hepatitis B Virus (HBV) Infection

Two types of products are available for prophylaxis against HBV infection. Hepatitis B vaccine, which provides long-term protection against HBV infection, is recommended for both preexposure and postexposure prophylaxis. Hepatitis B immune globulin (HBIG) provides temporary protection (i.e., 3-6 months) and is indicated only in certain postexposure settings.

Prevention of Perinatal Hepatitis B Virus Infection

1. All pregnant women should be routinely tested for hepatitis B surface antigen (HbsAg) during an early prenatal visit in each pregnancy, preferably at the same time other routine prenatal laboratory testing is done. HBsAg testing should be repeated late in the pregnancy for women who are HbsAg negative but who are at high risk of HBV infection (e.g., injecting drug users, those with intercurrent sexually transmitted diseases) or who have had clinically apparent hepatitis.

   Tests for other HBV markers are not necessary for the purpose of maternal screening. However, HBsAg- positive women identified during screening may have HBV-related liver disease and should be evaluated (CDC, 1991).

2. Infants born to mothers who are HBsAg positive should receive the appropriate doses of hepatitis B vaccine and HBIG (0.5 mL) within 12 hours of birth. Both should be administered by intramuscular injection. Hepatitis B vaccine should be administered concurrently with HBIG but at a different site. Subsequent doses of vaccine should be administered according to the recommended schedule.

3. Women admitted for delivery who have not had prenatal HBsAg testing should have blood drawn for testing. While test results are pending, the infant should receive hepatitis B vaccine within 12 hours of birth, in a dose appropriate for infants born to HBsAg-positive mothers.
    a. If the mother is later found to be HBsAg positive, her infant should receive the additional protection of HBIG as soon as possible and within 7 days of birth, although the efficacy of HBIG administered after 48 hours of age is not known (Beasley et al., 1983). If HBIG has not been administered, it is important that the infant receive the second dose of hepatitis B vaccine at 1 month and not later than 2 months of age because of the high risk of infection. The last dose should be administered at age 6 months.
    b. If the mother is found to be HBsAg negative, her infant should continue to receive hepatitis B vaccine as part of his or her routine vaccinations in the dose appropriate for infants born to HBsAg-negative mothers.
4. In populations in which screening pregnant women for HBsAg is not feasible, all infants should receive their first dose of hepatitis B vaccine within 12 hours of birth, their second dose at 1-2 months of age, and their third dose at 6 months of age as a part of their childhood vaccinations and well-child care.

Household contacts and sex partners of HBsAg-positive women identified through prenatal screening should be vaccinated. The decision to do prevaccination testing of these contacts to determine susceptibility to HBV infection should be made according to the guidelines in the section of the document "Prevaccination testing for susceptibility." Hepatitis B vaccine should be administered at the age-appropriate dose to those determined to be susceptible or judged likely to be susceptible to infection.

Universal Vaccination of Infants Born to HBsAg-Negative Mothers

1. Hepatitis B vaccination is recommended for all infants, regardless of the HBsAg status of the mother. Hepatitis B vaccine should be incorporated into vaccination schedules for children. The first dose can be administered during the newborn period, preferably before the infant is discharged from the hospital, but no later than when the infant is 2 months of age. Because the highest titers of anti-HBs are achieved when the last two doses of vaccine are spaced at least 4 months apart, schedules that achieve this spacing may be preferable. However, schedules with 2-month intervals between doses, which conform to schedules for other childhood vaccines, have been shown to produce a good antibody response and may be appropriate in populations in which it is difficult to ensure that infants will be brought back for all their vaccinations. The development of combination vaccines containing HBsAg may lead to other schedules that will allow optimal use of combined antigens.
2. Special efforts should be made to ensure that high levels of hepatitis B vaccination are achieved in populations in which HBV infection occurs at high rates among children (Alaskan Natives, Pacific Islanders, and infants of immigrants from countries in which HBV is endemic). Therefore, vaccination is recommended for all unvaccinated children aged less than 11 years who are Pacific Islanders or who reside in households of first generation immigrants from countries where HBV is of high or intermediate endemicity.

Recommendations for hepatitis B vaccination of newborn infants with thimerosal-containing vaccines and vaccines that do not contain thimerosal as a preservative

Mother's HBsAg status at delivery	Recommendation
Positive or Unknown	Vaccinate at birth. Use vaccine that does not contain thimerosal as a preservative; if unavailable, use thimerosal-containing vaccine.
Negative	Vaccinate at birth or by age 2 months. At birth, use vaccine that does not contain thimerosal as a preservative. At 2 months of age, use either thimerosal-containing vaccine or vaccine that does not contain thimerosal as a preservative.
Negative-High-risk*	Same as "Negative" above, except thimerosal-containing vaccine can be administered at birth.

* Populations or groups that have a high risk for early childhood hepatitis B virus (HBV) transmission, include Alaska Natives, Asian-Pacific Islanders, immigrant populations from countries in which HBV is of high or intermediate endemicity, and households with persons with chronic HBV infection.

CDC, Advisory Committee on Immunization Practices (ACIP). "Recommendations regarding the use of vaccines that contain thimerosal as a preservative." MMWR 1999 Nov 05; 48(43);996-8.

Expanded Childhood Vaccination Recommendations

In October 1994, the ACIP approved recommendations expanding the vaccination strategy to eliminate hepatitis B virus transmission in the United States. This includes:

- Vaccination of all unvaccinated children less than 11 years who are Alaska Natives, Pacific Islanders or who reside in households of first-generation immigrants from countries where HBV is of high or intermediate endemicity
- Vaccination of all 11-12-year-old children who have not previously received hepatitis B vaccine

In October 1997, the ACIP expanded these recommendations to include all unvaccinated children aged 0-18 years and made hepatitis B vaccine available through the Vaccines for Children program (VFC) for persons aged 0-18 years who are eligible for VFC.

ACIP priorities for hepatitis B vaccination of children remain unchanged and include:

- All infants
- Children in populations at high risk for hepatitis B virus infection (i.e., are Alaska Natives, Pacific Islanders or who reside in households of first-generation immigrants from countries where HBV is of high or intermediate endemicity)
- previously unvaccinated children aged 11-12 years
- older adolescents and adults in defined risk groups (see below)

Vaccination of Adolescents

All adolescents at high risk of infection because they are injecting drug users or have multiple sex partners (more than one partner/6 months) should receive hepatitis B vaccine. Widespread use of hepatitis B vaccine is encouraged. Because risk factors are often not identified directly among adolescents, universal hepatitis B vaccination of teenagers should be implemented in communities where injecting drug use, pregnancy among teenagers, and/or sexually transmitted diseases are common. Adolescents can be vaccinated in school-based clinics, community health centers, family planning clinics, clinics for the treatment of sexually transmitted diseases, and special adolescent clinics.

The 0-, 1-, and 6-month schedule is preferred for vaccinating adolescents with the age-appropriate dose of vaccine. However, the choice of vaccination schedule should take into account the feasibility of delivering three doses of vaccine over a given period of time. The use of alternate schedules (e.g., 0, 2, and 4 months) may be advisable to achieve complete vaccination.

Vaccination of Selected High-Risk Groups

Efforts to vaccinate persons at high risk of HBV infection should follow the vaccine doses shown below. High-risk groups for whom vaccination is recommended include:

1. Persons with occupational risk. HBV infection is an occupational hazard for health-care workers and for public-safety workers who have exposure to blood in the workplace (US Department of Labor, US Department of Health and Human Services, 1987; CDC, 1989). The risk of acquiring HBV infections from occupational exposures depends on the frequency of percutaneous and permucosal exposure to blood or blood-contaminated body fluids. Any health-care or public-safety worker may be at risk for HBV exposure, depending on the tasks he or she performs. Workers who perform tasks involving contact with blood or blood-contaminated body fluid should be vaccinated (US Department of Labor, Us Department of Health and Human Services, 1987; CDC, 1989; Department of Labor, 1989). For public-safety workers whose exposure to blood is infrequent, timely postexposure prophylaxis should be considered rather than routine preexposure vaccination. For persons in health-care fields, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions, before trainees have their first contact with blood.
2. Clients and staff of institutions for the developmentally disabled. Susceptible clients in institutions for the developmentally disabled, as well as staff who work closely with clients, should be vaccinated. Susceptible clients and staff who live or work in smaller residential settings with known HBV carriers

should also receive hepatitis B vaccine. Clients discharged from residential institutions into community programs should be screened for HBsAg so that appropriate measures can be taken to prevent HBV trans- mission. These measures should include both environmental controls and appropriate use of vaccine. Staff of nonresidential day-care programs for the develop- mentally disabled (e.g., schools, sheltered workshops) attended by known HBV carriers have a risk of infection comparable with that of health-care workers and therefore should be vaccinated (Breuer et al.,1985). The risk of infection for other clients appears to be lower than the risk for staff. Vaccination of clients in day care programs may be considered. Vaccination of classroom contacts is strongly encouraged if a classmate who is an HBV carrier behaves aggressively or has special medical problems (e.g., exudative dermatitis, open skin lesions) that increase the risk of exposure to his or her blood or serous secretions.

3. Hemodialysis patients. Hepatitis B vaccination is recommended for susceptible hemodialysis patients. Vaccinating patients early in the course of their renal disease is encouraged because patients with uremia who are vaccinated before they require dialysis are more likely to respond to the vaccine (Seaworth et al., 1988). Although their seroconversion rates and anti-HBs titers are lower than those of healthy persons, patients who respond to vaccination will be protected from infection, and the need for frequent serologic testing will be reduced (Moyer, Alter, & Favero, 1990).
4. Recipients of certain blood products. Patients who receive clotting-factor concentrates have an increased risk of HBV infection and should be vaccinated as soon as their specific clotting disorder is identified. Prevaccination testing is recommended for patients who have already received multiple infusions of these products.
5. Household contacts and sex partners of HBV carriers. All household and sexual contacts of persons identified as HBsAg positive should be vaccinated. The decision to do prevaccination testing to determine susceptibility to HBV infection should be made according to the guidelines described earlier in the section "Prevaccination testing for susceptibility." Hepatitis B vaccine should be administered at the age-appropriate dose to those deter- mined to be susceptible or judged likely to be susceptible to infection.
6. Adoptees from countries where HBV infection is endemic. Adopted or fostered orphans or unaccompanied minors from countries where HBV infection is endemic should be screened for HBsAg (Margolis, Alter, & Hadler, 1991). If the children are HBsAg positive, other family members should be vaccinated (Hershow, Hadler, & Kane, 1987).
7. International travelers. Vaccination should be considered for persons who plan to spend more than 6 months in areas with high rates of HBV infection and who will have close contact with the local population. Short-term travelers who are likely to have contact with blood (e.g., in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease should be vaccinated. Vaccination should begin at least 6 months before travel to allow for completion of the full vaccine series, although a partial series will offer some protection. The alternate four-dose schedule should provide protection if the first three doses can be delivered before departure.
8. Injecting drug users. All injecting drug users who are susceptible to HBV should be vaccinated as soon as their drug use begins. Because of the high rate of HBV infection in this population, prevaccination screening should be considered as outlined in the section "Prevaccination testing for

susceptibility." Injecting drug users known to have HIV infection should be tested for anti-HBs response after completion of the vaccine series. Those who do not respond to vaccination should be counseled accordingly.

9. Sexually active homosexual and bisexual men. Susceptible sexually active homosexual and bisexual men should be vaccinated. Because of the high rate of HBV infection in this population, prevaccination screening should be considered as described in the section "Prevaccination testing for susceptibility." Men known to have HIV infection should be tested for anti-HBs response after completion of the vaccine series. Those who do not respond to vaccination should be counseled accordingly.
10. Sexually active heterosexual men and women. Vaccination is recommended for men and women who are diagnosed as having recently acquired other sexually transmitted diseases, for prostitutes, and for persons who have a history of sexual activity with more than one partner in the previous 6 months (Alter et al., 1990). Most patients seen in clinics for sexually transmitted diseases should be considered candidates for vaccination.
11. Inmates of long-term correctional facilities. Prison officials should consider undertaking screening and vaccination programs directed at inmates with histories of high-risk behaviors.

Recommended doses of currently licensed hepatitis B vaccines

	Recombivax HB*		Engerix-B*	
Group	Dose (mg)	(mL)	Dose (mg)	(mL)
Infants of HbsAg[$]-negative mothers and children less than 11 years	2.5	(0.25)	10	(0.5)
Infants of HbsAg-positive mothers; prevention of perinatal infection	5	(0.5)	10	(0.5)
Children and adolescents 11-19 years	5	(0.5)	20	(1.0)
Adults greater than or equal to 20 years	10	(1.0)	20	(1.0)
Dialysis patients and other immunocompromised persons	40	(1.0)[&]	40	(2.0)[@]

* Both vaccines are routinely administered in a three dose series. Energix-B has also been licensed for a four-dose series administered at 0, 1, 2, and 12 months.

[$] HbsAg = hepatitis B surface antigen

[&] Special formulation

[@] Two 1.0 mL doses administered at one site, in a four-dose schedule at 0, 1, 2, and 6 months

Special Notice: On March 31, 2000 the CDC issued a notice recommending that the two-dose Recombivax HB hepatitis B vaccination schedule include adolescents aged 11-15 years. Using this schedule, the adult dose of Recombivax HB (1.0 mL dose containing 10 micrograms of hepatitis B surface antigen) is administered to adolescents aged 11-15 years, with the second dose given 4 to 6 months after the first dose. It is not known whether booster doses of vaccine will be required. Children and adolescents who have begun vaccination with a dose of 5 microgram of Recombivax HB should complete the three-dose series with this dose. If it is not clear which dose an adolescent was administered at the start of a series, the series should be completed with the three-dose schedule. (Notice to readers: Alternate two-dose hepatitis B vaccination schedule for adolescents aged 11-15 years. MMWR Morb Mortal Wkly Rep. 2000 Mar 31;49(12);261.)

For children and adults whose immune status is normal, booster doses of vaccine are not recommended, nor is serologic testing to assess antibody levels necessary. The possible need for booster doses will be assessed as additional information becomes available. For hemodialysis patients, vaccine-induced protection may be less complete and may persist only as long as antibody levels are >=10 mIU/mL. For these patients, the need for booster doses should be assessed by annual antibody testing, and a booster dose should be administered when antibody levels decline to <10 mIU/mL.

Hepatitis B vaccine should be administered only in the deltoid muscle of adults and children or in the anterolateral thigh muscle of neonates and infants. When hepatitis B vaccine is administered to infants at the same time as other vaccines, separate sites in the anterolateral thigh may be used for the multiple injections. This method is preferable to administering vaccine at sites such as the buttock or deltoid.

Postexposure Prophylaxis

Prophylactic treatment to prevent infection after exposure to HBV should be considered in the following situations: perinatal exposure of an infant born to an HBsAg-positive mother (see above), inadvertent percutaneous or permucosal exposure to HBsAg-positive blood, sexual exposure to an HBsAg- positive person, and household exposure of an infant 12 months of age to a primary care-giver who has acute hepatitis B.

Recommendations on postexposure prophylaxis are based on available efficacy data and on the likelihood of future HBV exposure for the person requiring treatment. In all exposures, a regimen combining HBIG with hepatitis B vaccine will provide both short- and long-term protection, will be less costly than the two-dose HBIG treatment alone, and is the treatment of choice.

Acute Exposure to Blood that Contains (or Might Contain) HBsAg

The outline below summarizes prophylaxis for percutaneous (needlestick, laceration, or bite) or permucosal (ocular or mucous-membrane) exposure to blood according to the HBsAg status of the source of exposure and the vaccination

status and vaccine response of the exposed person. For greatest effectiveness, passive prophylaxis with HBIG, when indicated, should be administered as soon as possible after exposure since its value beyond 7 days after exposure is unclear.

1. Source of exposure known and HBsAg positive
    a. Exposed person has not been vaccinated or has not completed vaccination. Hepatitis B vaccination should be initiated. A single dose of HBIG (0.06 mL/kg) should be administered as soon as possible after exposure and within 24 hours, if possible. The first dose of hepatitis B vaccine should be administered intramuscularly at a separate site (deltoid for adults) and can be administered simultaneously with HBIG or within 7 days of exposure; subsequent doses should be administered as recommended for the specific vaccine. If the exposed person has begun but has not completed vaccination, one dose of HBIG should be administered immediately and vaccination should be completed as scheduled.
    b. Exposed person has already been vaccinated against hepatitis B, and anti-HBs response status is known.
        1. If the exposed person is known to have had adequate response in the past, the anti-HBs level should be tested unless an adequate level has been demonstrated within the last 24 months. Although current data show that vaccine-induced protection does not decrease as antibody level wanes, most experts consider the following approach to be prudent: (a) If the anti-HBs level is adequate, no treatment is necessary; (b) If the anti-HBs level is inadequate (less than 10 mIU/mL), a booster dose of hepatitis B vaccine should be administered.
        2. If the exposed person is known not to have responded to the primary vaccine series, he or she should receive either a single dose of HBIG and a dose of hepatitis B vaccine as soon as possible after exposure, or two doses of HBIG (0.06 mL/kg), one as soon as possible after exposure and the second 1 month later. The latter treatment is preferred for those who have not responded to at least four doses of vaccine.
    c. Exposed person has already been vaccinated against hepatitis B, and the anti-HBs response is unknown. The exposed person should be tested for anti-HBs.
        1. If the exposed person has adequate antibody, no additional treatment is necessary.
        2. If the exposed person has inadequate antibody on testing, one dose of HBIG (0.06 mL/kg) should be administered immediately and a standard booster dose of vaccine administered at a different site.
2. Source of exposure known and HBsAg-negative
    a. Exposed person has not been vaccinated or has not completed vaccination. If unvaccinated, the exposed person should be administered the first dose of hepatitis B vaccine within 7 days of exposure, and vaccination should be completed as recommended. If the exposed person has not completed vaccination, vaccination series should be completed as scheduled.
    b. Exposed person has already been vaccinated against hepatitis B. No treatment is necessary.
3. Source of exposure unknown or not available for testing.

a. Exposed person has not been vaccinated or has not completed vaccination. If unvaccinated, the exposed person should be administered the first dose of hepatitis B vaccine within 7 days of exposure and vaccination should be completed as recommended. If the exposed person has not completed vaccination, vaccination should be completed as scheduled.
b. Exposed person has already been vaccinated against hepatitis B, and anti-HBs response status is known.
    1. If the exposed person is known to have had adequate response in the past, no treatment is necessary.
    2. If the exposed person is known not to have responded to the vaccine, prophylaxis as described above in section 1.b.(2) under "Source of exposure known and HBsAg-positive" may be considered if the source of the exposure is known to be at high risk of HBV infection.
c. Exposed person has already been vaccinated against hepatitis B, and the anti-HBs response is unknown. The exposed person should be tested for anti-HBs.
    1. If the exposed person has adequate anti-HBs, no treatment is necessary.
    2. If the exposed person has inadequate anti-HBs, a standard booster dose of vaccine should be administered.

Sex Partners of Persons with Acute Hepatitis B Virus Infection

All susceptible persons whose sex partners have acute hepatitis B infection should receive a single dose of HBIG (0.06 mL/kg) and should begin the hepatitis B vaccine series if prophylaxis can be started within 14 days of the last sexual contact or if sexual contact with the infected person will continue. Administering the vaccine with HBIG may improve the efficacy of postexposure treatment. The vaccine has the added advantage of conferring long-lasting protection.

An alternate treatment for persons who are not from a high-risk group for whom vaccine is routinely recommended and whose regular sex partners have acute HBV infection is to administer one dose of HBIG (without vaccine) and retest the sex partner for HBsAg 3 months later. No further treatment is necessary if the sex partner becomes HBsAg negative. If the sex partner remains HBsAg positive, a second dose of HBIG should be given and the hepatitis B vaccine series started.

Household Contacts of Persons with Acute Hepatitis B Virus Infection

Since infants have close contact with primary caregivers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant less than 12 months of age with HBIG (0.5 mL) and hepatitis B vaccine is indicated if the mother or primary caregiver has acute HBV infection. Prophylaxis for other household contacts of persons with acute HBV infection is not indicated unless they have had identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors. Such exposures should be treated like sexual exposures. If the index patient becomes an HBV carrier, all household contacts should receive hepatitis B vaccine.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Universal childhood vaccination:

Immunization with hepatitis B vaccine is the most effective means of preventing hepatitis B virus (HBV) infection and its consequences. Integrating hepatitis B vaccine into childhood vaccination schedules has been shown to interrupt HBV transmission. Clinical trials of the hepatitis B vaccines licensed in the United States have shown that they are 80%-95% effective in preventing HBV infection and clinical hepatitis among susceptible children and adults. If a protective antibody response develops after vaccination, vaccine recipients are virtually 100% protected against clinical illness.

Postexposure Prophylaxis for Hepatitis B

Various studies have established the relative efficacies of HBIG and/or hepatitis B vaccine in different exposure situations. For an infant with perinatal exposure to an HbsAg-positive and HbeAg-positive mother, a regimen combining one dose of HBIG at birth with the hepatitis B vaccine series started soon after birth is 85-95% effective in preventing development of the HBV carrier state. Regimens involving either multiple doses of HBIG alone or the vaccine series alone have 70%-90% efficacy.

For inadvertent percutaneous exposure, only regimens including HBIG an/or immune globulin (IG) have been studied. A regimen of two doses of HBIG, one given after exposure and one a month later is about 75% effective in preventing hepatitis B in this setting. For sexual exposure to a person with acute hepatitis B, a single dose of HBIG is 75% effective if administered within 2 weeks of last sexual exposure. IG no longer has a role in postexposure prophylaxis of hepatitis B because of the availability of HBIG and the wider use of hepatitis B vaccine.

POTENTIAL HARMS

Pain at the injection site (3%-29%) and a temperature greater than 37.7^{o} C (1%-6%) have been among the most frequently reported side effects among adults

and children receiving vaccine. In placebo-controlled studies, these side effects were reported no more frequently among vaccinees than among persons receiving a placebo. Among children receiving both hepatitis B vaccine and DTP vaccine, these mild side effects have been observed no more frequently than among children receiving DTP vaccine alone.

As of November 1999, several vaccines containing thimerosal, a mercury-based preservative, were still available despite progress in developing thimerosal-free formulations. However, the risk, if any, to infants from exposure to thimerosal is believed to be slight. The demonstrated risks for not vaccinating children far outweigh the theoretical risk for exposure to thimerosal-containing vaccines during the first 6 months of life.

In the United States, surveillance of adverse reactions has shown a possible association between Guillain-Barre syndrome (GBS) and receipt of the first dose of plasma-derived hepatitis B vaccine. GBS was reported at a very low rate (0.5/100,000 vaccinees), no deaths were reported, and all reported cases were among adults. An estimated 2.5 million adults received one or more doses of recombinant hepatitis B vaccine during the period 1986-1990. Available data from reporting systems for adverse events do not indicate an association between receipt of recombinant vaccine and GBS.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Update: recommendations to prevent hepatitis B virus transmission--United States. MMWR Recomm Rep 1999 Jan 22;48(2):33-4. [7 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Jan 22

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Committee Members, October 1997: Not stated

Names of Committee Members, September 1991: Samuel L. Katz, MD; John La Montagne, PhD; Carolyn Hardegree, MD; Claire V. Broome, MD; Ronald C. Van Buren, MD; Stanley E. Broadnax, MD; James D. Cherry, MD; Georges Peter, MD; Caroline B. Hall, MD; Mary Lou Clements, MD; Pierce Gardner, MD; David W. Fraser, MD; William Schaffner, MD; Edward A. Mortimer, Jr., MD; Carlos E. Hernandez, MD; Susan E. Tamblyn, MD, Dr PH; Gregory R. Istre, MD; Carlos H. Ramirez-Ronda, MD; Michael Peterson, DVM; Mary E. Wilson, MD; Kenneth J. Bart, MD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It provides updated recommendatiosn to the previous guidelines issued by the Centers for Disease Control and Prevention (CDC):

1. Update: recommendations to prevent hepatitis B virus transmission--United States. MMWR Morb Mortal Wkly Rep. 1995 Aug 4;44(30):574-5. Available from the Centers for Disease Control and Prevention Web site.
2. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination. MMWR Morb Mortal Wkly Rep. 1991 Nov 22;40(RR-13):1-25. Available from the Centers for Disease Control and Prevention Web site.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention Web site.

Print copies: Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

1. Update: recommendations to prevent hepatitis B virus transmission--United States. MMWR Morb Mortal Wkly Rep. 1995 Aug 4;44(30):574-5. Available from the Centers for Disease Control and Prevention Web site.
2. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination. MMWR Morb Mortal Wkly Rep. 1991 Nov 22;40(RR-13):1-25. Available from the Centers for Disease Control and Prevention Web site.

Print copies: Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325.

PATIENT RESOURCES

None available

NGC STATUS

The summary was completed by ECRI on December 1, 1999. This information was verified by the guideline developer on May 1, 2000.

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Date Modified: 5/10/2004